

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI

MARIANNE PRATHER,

Plaintiff,

v.

ORGANON USA, INC., ORGANON  
PHARMACEUTICALS USA, INC.,  
ORGANON INTERNATIONAL, INC.,  
AKZO NOBEL NV and SCHERING-  
PLOUGH CORPORATION,

Defendants.

) 4:08-cv-0558-RWS  
)  
) IN RE NUVARING® PRODUCTS  
) LIABILITY LITIGATION  
)  
) 4:08-MDL-1964-RWS  
)  
)  
) *DOCUMENT ELECTRONICALLY FILED*  
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)

**DECLARATION OF MELISSA A. GEIST IN SUPPORT OF DEFENDANTS'**  
**MOTION FOR SUMMARY JUDGMENT**

I, Melissa A. Geist, declare:

1. I am an adult resident of the Commonwealth of Pennsylvania and an attorney with Reed Smith LLP, counsel for Organon USA, Inc., Organon Pharmaceuticals USA, Inc. LLC (f/k/a Organon Pharmaceuticals USA, Inc.), Organon International, Inc. and Merck & Co., Inc. (f/k/a Schering-Plough Corporation), (collectively “Defendants”) in this MDL proceeding.

2. Attached hereto as Exhibit 1 is a true and correct copy of the FDA Approved Label for NuvaRing®.

3. Attached hereto as Exhibit 2 is a true and correct copy of the relevant excerpts of the Expert Report of Dr. Nicholas A. Flavahan, Ph.D.

4. Attached hereto as Exhibit 3 is a true and correct copy of FDA Medical Officer’s Review, October 6, 2000.

5. Attached hereto as Exhibit 4 is a true and correct copy of FDA Group Leader Memorandum, December 22, 2000.

6. Attached hereto as Exhibit 5 is a true and correct copy of the relevant excerpts of the Supplemental NuvaRing® MDL Expert Opinion, Joseph Shumway, M.D., MPH, FACOG.

7. Attached hereto as Exhibit 6 is a true and correct copy of the relevant excerpts of the Deposition of Dr. Steven B. Shohet, M.D., dated October 6, 2011.

8. Attached hereto as Exhibit 7 is a true and correct copy of the relevant excerpts of the Deposition of Dr. Scott Roseff, M.D., FACOG, dated October 10, 2011.

9. Attached hereto as Exhibit 8 is a true and correct copy of the relevant excerpts of the Expert Report of Dr. David A. Grimes, M.D., FACOG, FACPM, FRCOG (Hon.).

10. Attached hereto as Exhibit 9 is a true and correct copy of the relevant excerpts of the Deposition of Dr. John M. Richart, M.D., dated October 21, 2011.

11. Attached hereto as Exhibit 10 is a true and correct copy of the relevant excerpts of the report of Plaintiffs' expert Stephen B. Shohet, M.D.

12. Attached hereto as Exhibit 11 is a true and correct copy of the relevant excerpts of the Deposition of Dr. Joseph Shumway, M.D., MPH, FACOG., dated October 19, 2011.

13. Attached hereto as Exhibit 12 is a true and correct copy of the article by the World Health Organization, *Effect of Different Progestagens in Low Oestrogen Oral Contraceptives on Venous Thromboembolic Disease*, 346 *The Lancet* 1582 (1995).

14. Attached hereto as Exhibit 13 is a true and correct copy of the article by Hershel Jick et al., *Risk of Idiopathic Cardiovascular Death and Nonfatal Venous Thromboembolism in Women Using Oral Contraceptives with Differing Progestagen Components*, 346 *The Lancet* 1589 (1995).

15. Attached hereto as Exhibit 14 is a true and correct copy of the article by Walter O. Spitzer et al., *Third Generation Oral Contraceptives and Risk of Venous Thromboembolic Disorders; An International Case-Control Study*, 213 *BMJ* 83 (1996).

16. Attached hereto as Exhibit 15 is a true and correct copy of the article by Dillner L., *Pill Scare Linked to Rise in Abortions*, 312 *British Medical Journal* 996 (1996).

17. Attached hereto as Exhibit 16 is a true and correct copy of the article by A. Furedi, *The Public Health Implications of the 1995 'Pill Scare'*, 5 *Human Reproduction Update* 621 (1999).

18. Attached hereto as Exhibit 17 is a true and correct copy of the article by Samy Suissa et al., *First-Time Use of Newer Oral Contraceptives and the Risk of Venous Thromboembolism*, 56 *Contraception* 141 (1997).

19. Attached hereto as Exhibit 18 is a true and correct copy of the article by S. Suissa et al., *Recurrent Use of Newer Oral Contraceptives and the Risk of Venous Thromboembolism*, 15 Human Reproduction 817 (2000).

20. Attached hereto as Exhibit 19 is a true and correct copy of the article by Michael A. Lewis, *The Transnational Study on Oral Contraceptives and the Health of Young Women*, 5 Human Reproduction Update 707 (1999).

21. Attached hereto as Exhibit 20 is a true and correct copy of the relevant excerpts of the Expert Report of Professor Samy Suissa.

22. Attached hereto as Exhibit 21 is a true and correct copy of the Letter To FDA, December 28, 1999 and NDA Table of Contents.

23. Attached hereto as Exhibit 22 is a true and correct copy of the 1994 Labeling Guidance for Combined Oral Contraceptives ("1994 Guidance").

24. Attached hereto as Exhibit 23 is a true and correct copy of the 1988 Labeling Guidance for Combined Oral Contraceptives.

25. Attached hereto as Exhibit 24 is a true and correct copy of the December 28, 1999 Proposed NuvaRing® Label.

26. Attached hereto as Exhibit 25 is a true correct copy of the November 22, 2000 FDA Draft NuvaRing® Label.

27. Attached hereto as Exhibit 26 is a true and correct copy of the Addendum to Original Medical Officer's Review, Dec. 18, 2000.

28. Attached hereto as Exhibit 27 is a true and correct copy of the December 22, 2000 NuvaRing® Approvable Letter.

29. Attached hereto as Exhibit 28 is a true and correct copy of the April 17, 2001 FDA Draft NuvaRing® Label.

30. Attached hereto as Exhibit 29 is a true and correct copy of the October 3, 2001 FDA Approval Letter.

31. Attached hereto as Exhibit 30 is a true and correct copy of the relevant excerpts of the Deposition of Evelyne Schuetz, M.D.

32. Attached hereto as Exhibit 31 is a true and correct copy of the relevant excerpts of the Deposition of Marianne Prather.

33. Attached hereto as Exhibit 32 is a true and correct copy of the relevant excerpts of the Deposition of Robert E. Kraetsch, M.D.

34. Attached hereto as Exhibit 33 is a true and correct copy of the John M. Richart, M.D. Case Specific Expert Report For Marianne Prather.

35. Attached hereto as Exhibit 34 is a true and correct copy of the relevant excerpts of the Deposition of Teri St. Clair.

36. Attached hereto as Exhibit 35 is a true and correct copy of the relevant excerpts of the Deposition of Gerald Joseph Mann.

37. Attached hereto as Exhibit 36 is a true and correct copy of the Expert Report of Charles Eby, M.D. In Marianne Prather Case.

38. Attached hereto as Exhibit 37 is a true and correct copy of the relevant excerpts of the Plaintiff's Fact Sheet.

39. Attached hereto as Exhibit 38 is a true and correct copy of the relevant excerpts of the Deposition of John M. Richart, M.D., dated November 18, 2011.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct, and that this declaration was executed on this 2nd day of November, 2012, in Princeton, New Jersey.

/s/ Melissa A. Geist  
Melissa A. Geist

**CERTIFICATE OF SERVICE**

I hereby certify that on this 2nd day of November, 2012, I filed the foregoing via the Court's electronic case filing system, which will cause it to be served on the counsel of record.

/s/ Melissa A. Geist